

# Exhibit 4

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

MDL No. 19-2875

This document relates to:  
*All Actions*

ORDER NO. \_\_\_\_

THIS MATTER having been opened to the Court by Plaintiffs for entry of an order granting their motions in limine, and the Court having considered the submissions of the Parties, and for good cause shown:

For the reasons stated on the record during the July 23, 2024 case management conference, it is hereby ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2024 that Plaintiffs' motions in limine are decided as follows:

1. Defendants cannot assert that it is not appropriate to perform a retrospective analysis of their conduct or the consequences, including for example the resulting adulteration of the contaminated API and VCDs.

~~Granted. (7/23/2024 Tr. 172:13-20).~~

Plaintiffs' amended position:

Granted. Defendants cannot argue that it would be inappropriate to do a retrospective analysis of their conduct or the consequences, including to determine whether the drug was adulterated before the FDA findings, or argue that the drug was not adulterated until the FDA declared it was

adulterated, and cannot argue that the only way a drug can be adulterated is when the FDA makes that finding. Defendants can present evidence and argument that the drugs were not adulterated prior to or in the absence of any FDA finding (7/23/24 Tr. 169:14-22, 171:7-172:20).

**Defendants' Position:**

Granted. Defendants cannot assert that it is not appropriate to perform a retrospective analysis to determine if the drug was adulterated. However, Defendants can present evidence and argument that the drugs were not adulterated prior to or in the absence of any FDA finding. (7/23/2024 Tr. 155:19 - 172:20).

2. Defendants cannot defend their conduct by pointing to lack of knowledge or action by the FDA prior to ZHP's disclosure of the contamination in June 2018, or blame or point the finger at the FDA in any way as a defense or excuse for their conduct.

~~Granted in part, denied in part. Defendants can discuss the facts concerning what the FDA did or did not do, but they cannot argue that the FDA's action or inaction is a defense to Plaintiffs' claims. (7/23/2024 Tr. 185:22-186:5).~~

**Plaintiffs' Amended Position:**

Granted in part, denied in part. Defendants can discuss the facts concerning what was submitted to the FDA and what the FDA did, however Defendants cannot blame the FDA for the contamination (7/23/24 Tr. 180:9-181:21, ). Defendants cannot argue that the FDA found that there was no problem with the API and/or had no concern about impurities including nitrosamines and NDMA, based on its review of the ANDA or DMF (7/23/24 Tr. 183:6-184:14), and Defendants cannot argue that the findings in the FDA Warning Letter, which ZHP did not appeal, were wrong (7/23/24 Tr. 174:19-177:18).

**Defendants' Position:**

Denied. (7/23/2024 Tr. 185:22-186:7; 188:22-25).

3. Defendants cannot blame third-parties, including prescribing physicians, the FDA, or others, for the damages at issue.

**Granted; however, Defendants may discuss the fact that physicians**

prescribed the VCDs and after the recall would have prescribed something else in their absence. (7/23/2024 Tr. 189:3-11).

4. Defendants cannot assert that the FDA statement advising patients not to discontinue their use of the VCDs until they could obtain a prescription for a replacement medication or treatment meant that the FDA did not believe that there was an unacceptable health risk due to the contamination of the VCDs.

**Granted.** Defendants can present evidence that the FDA told people to continue taking their VCDs until they were prescribed a replacement medication, but cannot say that this was because by definition, therefore, the FDA believed the VCDs were it was not adulterated and/or that there was no unacceptable health risk. (7/23/2024 Tr. 189:17-24, 190:17-193:51:1, 192:13-16 193:24).

5. The FDA information statements regarding the valsartan and other sartans' contamination should not be referenced, or used to defend or deflect liability. For example, ZHP cannot assert that they excuse ZHP's violations of cGMPs since one of the statements explicitly notes ZHP's violations and the Warning Letter, and they do not excuse the sale of the contaminated VCDs, all of which were recalled due to the contamination.

**Denied in part, reserved in part, without prejudice as to a limiting instruction ~~concerning~~ regarding** the relevance of the FDA's statements, if warranted during trial. (7/23/2024 Tr. 195:1-24).

6. Defendants cannot assert that there was an industry-wide problem, or that industry standards did not require them to identify and control all genotoxic impurities from their manufacturing processes.

**Granted in part, Denied in part, reserved in part, Defendants cannot argue that industry practice governed their conduct, as opposed to cGMP requirements, and without prejudice as to a limiting instruction regarding the relevance of industry practice, if Gwarranted during trial.** (7/23/2024 Tr. 195:25-196:17).

7. ZHP Defendants cannot disclose or rely on hearsay discussions with Jinsheng Lin, Ph.D, or other sources, to assert translation or interpretation of the July 27, 2017 email that differs from 30(b)(6) testimony of Min Li, or ZHP's translation.

Granted ~~to the extent that neither Jucai Ge, nor any other non expert witness, may offer hearsay testimony.~~ (7/23/2024 Tr. 197:8-199:318).

8. Defendants cannot assert or argue that NDMA and NDEA are not, and were not known to be at all relevant times, genotoxic, probable human carcinogens.

Granted; ~~however Defendants are permitted to introduce evidence or argument as to dosage response.~~ (7/23/2024 Tr. 199:5-200:14200:12-14).

9. General causation is not an element of the claims at issue, and is not an issue to be determined at trial.

~~Granted. "The relevant question is not whether [valsartan] causes cancer or not." The relevant question is "whether or not the presence of this carcinogen is enough to...present an unacceptable risk. Not whether it causes [cancer] or not."~~ (7/23/2024 Tr. 212:7-14, 215:20-216:13, 218:15-221:15).

[Reserved for M&C; We do not agree this was granted.]

10. Defendants cannot reference or assert the Valisure Citizen Petition, in any way, including but not limited to with regard to Dr. Najafi, nor can they use the Valisure Citizen Petition to assert that brand diovan contained NDMA or NDEA.

Plaintiffs' Amended Position:

Granted in part, denied in part, The Valisure Citizen Petition shall not be referenced, however Dr. Najafi can be asked if he did an independent analysis of Diovan, without reference to Valisure, and if he says no, or I don't know, then Defendants shall not ask any other questions on this issue. (7/23/2024 Tr. 225:14-227:9).

Granted in part; denied in part ~~only to the extent.~~ Dr. Najafi may be asked one question ~~regarding his knowledge of his limited validation of the results in the~~ the Valisure Citizen Petition ~~and his validation of results reported in the petition.~~ (7/23/2024 Tr. 225:14-22, 226:13-16, 226:22-24).

11. Defendants cannot argue that the specifications for the valsartan API and VCD's permitted the NDMA and NDEA contamination/that the specifications did not prohibit the NDMA and NDEA contamination.

**Denied, but it will be allowed "in [a] very limited" way. (7/23/2024 Tr. 228:23-25).**

12. Defendants cannot argue that their VCDs were not adulterated because they complied with the USP monograph for valsartan.

**Denied, but such evidence and argument will be allowed "in [a] very limited" way. (7/23/2024 Tr. 228:23-25, 229:8).**

13. Defendants cannot argue "all drugs have impurities."

**Denied. (7/23/2024 Tr. 230:8-9).**

14. Defendants cannot refer to the "alleged" presence of "purported impurities" or similar language, or dispute that all of the at-issue valsartan was contaminated, including untested lots (if any) at levels above the limits set by the FDA.

**Granted; however, Defendants are not precluded from arguing that the amount of impurities in the at-issue valsartan did not pose an unacceptable risk. (7/23/2024 Tr. 230:11-231:3-4).**

15. Defendants filed no cross-claims for contribution/indemnification, and disclosed no experts to do so, and should be precluded from asserting evidence or making arguments consistent therewith, including that a co-defendant was at fault, or liable for Plaintiffs' damages.

**Granted as to Defendants "blaming" one another, but denied as to Defendants "differentiating" one another. (7/23/2024 Tr. 231:18-232:11).**

16. Defendants cannot assert the cost of replacement drugs or therapies.

**Reserved and further briefing ordered. (7/23/2024 Tr. 237:18-21).**

17. Defendants cannot assert that the contaminated VCD's had value based on

their efficacy.

**Denied.** (7/23/2024 Tr. 205:14-15).

18. Defendants cannot reference, assert, or rely on opinions of defense experts that rely on the precluded opinions of other defense experts. For example, Dr. Afnan's opinions that rely on Dr. Xue's precluded opinions.

**Granted as unopposed, in principle, but reserved with respect to Dr. Afnan pending his Daubert hearing.** (7/23/2024 Tr. 239:3-5).

**Commented [A51]:** The Court did not reserve re Dr. Afnan. The Court simply observed that this is one of the issues raised as to Dr. Afnan. The Court did not suggest that this ruling would not apply to Dr. Afnan.

19. Defendants cannot argue that the relevant warranties only went to the prescribers.

**Granted.** (7/23/2024 Tr. 239:20).

20. Defendants cannot argue they are good companies, the "societal benefits" of their VCDs and other products, or the cost of drug research and development.

**Denied, but ~~such~~ evidence and argument will be limited if necessary by the Court at trial, and Defendants do so at their peril with regard to the Plaintiffs' responses.** (7/23/2024 Tr. 241:1-3, 241:10-11).

21. Defendants cannot postulate a "but-for" world in which the contamination was disclosed earlier and the contaminated API and VCDs would have remained available for purchase.

**Granted.** (7/23/2024 Tr. 242:3-4).

22. Defendants cannot reference double or treble damages, attorney fees, statutory penalties, pre- or post-judgment interest.

**Granted.** (7/23/2024 Tr. 242:12).

23. Defendants cannot argue they complied with SOPs, guidances, or regulations without specifically identifying same; and specifically-referenced SOPs must have been produced in discovery.

**Granted; however, Defendants will be allowed to state in openings and related arguments that they complied with applicable regulations, specifications, etc.** (7/23/2024 Tr. 242:14-23; 243:2-11).

24. Defendants cannot refer to their API or VCDs as “life saving” or similar descriptions.

**Denied.** (7/23/2024 Tr. 243:18-244:2).

25. Defendants cannot assert or argue that the prescription of VCDs was standard of care.

**Moot, as Defendants agreed.** (7/23/2024 Tr. 244:19-23).

26. ZHP Defendants cannot assert any evidence or argument inconsistent with their filed stipulations.

**Granted in that no party may “assert any evidence or any argument that ~~Granted~~ is inconsistent with their stipulations.”** (7/23/2024 Tr. 245:2-4).

27. Defendants cannot argue that Teva’s and Torrent’s VCDs were not adulterated because the FDA did not issue Warning Letters to them.

**Granted.** See ruling on Plaintiffs’ MIL 12 above. (7/23/2024 Tr. 245:5-10).

28. Defendants cannot argue that they complied with cGMPs’ in the manufacture of the API and VCDs.

**Denied, subject to the guidance on other MILs.** (7/23/2024 Tr. 245:~~11-18~~13-14).

29. Defendants cannot argue that the contaminated API and VCDs were not adulterated.

**Denied, subject to the guidance on other MILs.** (7/23/2024 Tr. 245:19-20).

30. Defendants cannot argue that the contamination was unavoidable or unforeseeable.

**Denied.** (7/23/2024 Tr. 246:21-246:1).

31. Defendants cannot argue that Teva’s and Torrent’s VCDs were not



adulterated because the FDA never declared their VCDs did not meet USP standards or never de-listed the VCDs from the Orange Book.

**Denied ~~as moot~~.** (7/23/2024 Tr. 246:2-7). [See rulings on Pltf. MILs #1, 11-13. 246:21-5.](#)

32. Teva and Torrent cannot argue that they were not responsible for the quality of the API incorporated into their finished dose VCDs.

**Granted in part, denied in part.** [Teva and Torrent are permitted to offer evidence make arguments about what they manufactured and that they purchased and incorporated API purchased from ZHP in the finished dose, their responsibilities with respect to finished dose but cannot argue that they were not responsible for the finished dose they sold, including the API incorporated therein.](#) See the decision on Plaintiffs' MIL 15 above. (7/23/2024 Tr. 246:8-247:1411).

33. Defendants cannot raise the notice issues raised on the dispositive motions at trial.

**Moot in light of the Court's Summary Judgment Opinion finding notice requirements satisfied as a matter of law.** (7/23/2024 Tr. 247:15-19).

34. Defendants cannot assert irrelevant, confusing, misleading, or unduly prejudicial background facts about MSP or its assignors, including but not limited to:
- a. The Litigation Between Life Wallet and Cano Health ("Cano"),
  - b. Reported Investigations by the S.E.C. and United States Attorney's Office for the Southern District of Florida into Life Wallet,
  - c. MSP's Business Model,
  - d. LifeWallet's Financial Condition, and
  - e. Issues Related to MSP's Assignors; and
  - f. Defendants Cannot Argue that MSP Is Merely an Assignee of SummaCare and Emblem and That It Is Not a Health Plan That Paid

for Valsartan.

**Granted, ~~but issue of the~~ in that no party may make arguments that are irrelevant, confusing, misleading, or unduly prejudicial about any other party. (7/23/2024 Tr. 248:3-249:15). The issue raised by Defendants with regard to the validity of validity of Plaintiff's assignments, ~~however,~~ has been referred to Judge Vanaskie for assessment. (7/23/2024 Tr. 248:249:16-1, 257:15-16).**

35. Defendants cannot argue or suggest that TPP Trial Subclass Plaintiffs/Members will retain any benefit and not pass it along to their insureds.

**Granted. ~~Moot, as~~ Defendants agreed they will not make that argument. not to make or suggest this argument. (7/23/2024 Tr. 257:20-258:4).**

36. Defendants cannot argue Medicare Part D Offsets (collateral source; reconciliation process).

**Reserved pending the Daubert hearings for the Parties' damages experts. (7/23/2024 Tr. 258:6-10).**

37. Defendants cannot suggest that there should be set offs for unquantified, speculative subsidies and reimbursements.

**Reserved pending the Daubert hearings for the Parties' damages experts. (7/23/2024 Tr. 258:12).**

38. Defendants cannot reference the dollar amounts for which they sold the API and VCDs, and the amounts of the reimbursements requested and/or agreed to with regard to downstream customers.

**Reserved pending the Daubert hearings for the Parties' damages experts. (7/23/2024 Tr. 258:18).**

39. Defendants cannot disparage the insurance industry.

**Granted. (7/23/2024 Tr. 258:19-20).**

40. The Court should not permit Defendants to discuss how a verdict would

economically affect either Defendants or society. This sort of conjecture is non-probative, prejudicial, and should be excluded.

**Granted in part, denied in part to the extent the economic effect on Defendants is relevant to punitive damages. (7/23/2024 Tr. 258:21-259:6).**

41. Defendants cannot argue TPP Trial Subclass Plaintiffs/Members are “sophisticated users” (see affirmative defense).

**~~Granted~~ Granted. Moot, as Defendants agreed. (7/23/2024 Tr. 259:12-13).**

42. Defense counsel should be barred from suggesting that they are one in the same as Defendants by using the terms “we,” “us,” and/or “our” when referring to Defendants. Such statements are irrelevant, inaccurate, and prejudicial.

**Moot, as Defendants are not going to make such statements. (7/23/2024 Tr. 259:16-18).**

43. Defendants cannot criticize plaintiff attorneys, plaintiffs for bringing lawsuits, or reference attorney advertising.

**Granted in that no attorney shall deride or criticize any other attorney. (7/23/2024 Tr. 259:19-260:7).**

44. The manner in which Plaintiff learned about this litigation or their attorneys, and when or why they retained their attorneys to represent them, is irrelevant and unrelated to Plaintiff’s claims and subject to attorney-client privilege.

**Granted in that no attorney shall deride or criticize the other parties. (7/23/2024 Tr. 260:12-13).**

45. Defendants cannot inject arguments regarding the consumers’ damages or suggest consumers benefitted.

**Granted, however, ~~(7/23/2024 Tr. 261:5).~~ Defendants can discuss evidence and make arguments regarding efficacy and economic worth to the extent otherwise permitted with regard to the value of the drugs. (7/23/2024 Tr. 260:23-261:5).**

46. Defendants cannot seek sympathy for big corporations targeted in litigation, or assert that they employ people in New Jersey.

**Granted. (7/23/2024 Tr. 261:7-8).**

/s/

Hon. Renée Marie Bumb, U.S.D.J.